



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 17 1999

Food and Drug Administration
Rockville MD 20857

4244 '99 JUN 21 A10:18

Mr. Robert L. Bogomolny
Corporate Senior Vice President
G. D. Searle & Company
5200 Old Orchard Road
Skokie, IL 60077

Re: Docket Nos. 99P-1173/CP1 and 98N-0056

Dear Mr. Bogomolny:

This letter responds to your citizen petition submitted on April 28, 1999, requesting that the Food and Drug Administration (FDA) add celecoxib to the priority section of the List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population (Docket No. 98N-0056). The Agency has evaluated your petition and concluded that celecoxib meets the criteria for inclusion on the priority section of the list. Accordingly, your petition is granted. FDA has added celecoxib to the priority section of the list for the indication rheumatoid arthritis.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-1173

PAV1

CROSS FILE SHEET

File Number: 99P\1173/PAV1

See File Number: 98N-0056/LET7